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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,129	03/23/2006	Hansell H Stedman	UPNQ3278USA	8761

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EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
01/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,129	STEDMAN ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17,21-24 and 33-45* is/are pending in the application.

4a) Of the above claim(s) *15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24 and 33-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/7/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by van Moorlegem et al (6,776,771).

a. Regarding claim 21, van Moorlegem discloses inflatable balloons 5/9 that has an interior and expands radially without significant distal expansion (see figure 2). The outer balloon 9 when inflated forms an elongate, continuous cylindrical tube having an outer diameter that is substantially constant along a full length of the tube and is capable of abutting the walls of a vessel 3 in which it has been inserted to occlude blood flow through both the main vessel and branch vessels of the main vessel (see figure 1). A flexible cannula 0 has a distal and

proximal end and extends along an axis having an internal channel 4 for controlled application of fluid under pressure. The balloon 5/9 is attached to the cannula at least at two points (see figure 2) one point of attachment being adjacent the distal end of the cannula and a second point being adjacent to the proximal end of the cannula (see figures 1 and 2). The device is capable of occluding the aortic space or vena cavae by sealing with the vessel walls.

b. Regarding claim 22, see figure 2, which shows the balloon attached at three or more locations along the cannula 2.

c. Regarding claim 23, see figures 2 and 3, which show at least two compartments 5 formed by multiple points of attachment.

d. Regarding claim 24, figure 2 shows six compartments formed by multiple points of attachment, with all but the outermost compartments being intermediate. The intermediate compartments are capable of being distended less than the other compartments. One reason would be different external pressures applied to the balloon, causing the balloon to not fill as much as other balloon segments with no less forces applied to them. Alternatively, van Moorlegem discloses an inflation gradient of axial variations in the expansion of the chambers (Col.5 lines 57-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,728,066).

e. Regarding claim 34, Daneshvar discloses a flexible elongate cannula 35 having distal and proximal ends and extending along an axis with an internal channel for the application of fluid (Col.1, lines 10-13). An inflatable and radially expandable balloon 36 is attached to the cannula and extends from adjacent the distal end to adjacent the proximal end of the cannula. When inflated, the balloon forms an elongate, continuous and substantially cylindrical tube along its full length. While Daneshvar substantially discloses the apparatus as claimed, it does not disclose the balloon extending the length of the entire aorta. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the balloon of Daneshvar because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Daneshvar because Daneshvar discloses the balloon barrier being used in all portions of the aorta, including the ascending aorta, aortic arch and descending aorta (Col.17 lines 63-67). Daneshvar further discloses the balloon size, shape and location as being variable depending on intended use (Col.19 lines 11-13) and that the balloon may be adjustable to allow the position to be changed (Col.19 lines 1-3).

Therefore, it would have been an obvious matter of design choice to modify Daneshvar to obtain the invention as specified in claim 34.

f. Regarding claim 35, Daneshvar discloses the catheter body may have a J-shaped ending to prevent from damaging the wall of the vessel (Col.6 lines 59-61). See claim 34 regarding elongation of the balloon. Applying a J shape to the balloon would also prevent the balloon from damaging the wall of the vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the elongated balloon of Daneshvar in a J-shape to prevent it from damaging the wall of the vessel.

g. Regarding claim 36, Daneshvar further discloses various figures showing the bend of the catheter and it being located within the aortic arch (figures 4-6 and 11-14).

h. Regarding claim 37, from figure 6 it is apparent the curve is subtending an angle of approximately 180^{o}.

i. Regarding claim 38, figure 7 shows three different lumens, one is capable of serving as a vent during vector recirculation and both tips of catheters/lumens 35 and 42 are open to a vessel lumen.

j. Regarding claim 39, while Daneshvar substantially discloses the apparatus as claimed, it does not disclose the exact measurements of the catheter. However, Daneshvar does acknowledge that the aorta size varies in different people (Col.10 lines 42-44) and that a proper curvature of the distal end is desired to place it within certain parts of the aorta (Col.17 lines 8, 22, 27 and

35). Finally, Daneshvar discloses varying the balloon size, shape and location depending on its intended use (Col.19 lines 11-13). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the curvature of the distal arc, length of the balloon envelope and diameter of the tube, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

k. Regarding claim 40, figures 6-8 show the balloon as a single, continuous balloon with uninterrupted internal space for expansion fluid.

3. Claims 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,728,066) as applied to claim 40 above, and further in view of van Moorlegem et al (6,776,771).

l. Regarding claim 41, while Daneshvar substantially discloses the apparatus as claimed, it does not disclose the balloon being a series of separate balloon segments disposed end-to-end with no gaps therebetween. However, van Moorlegem discloses an adaptive balloon catheter that may be used in the aorta (Col.1 line 55) with a series of separate balloon segments (Col.3 lines 17-19). Further disclosed is that the opposing flanges can be parallel to each other (Col.4 lines 60 and 61, and figure 1) and further discusses varying the length of hinges 7 (Col.4 lines 35-37). Thus varying the length as suggested by Daneshvar offers a finite number of options, including shortening the hinges such that there

are no gaps between the balloons. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Daneshvar with separate balloon segments with no gaps therebetween as taught by van Moorlegem in order to introduce an adaptive balloon with improved flexibility.

m. Regarding claim 42, see claims 34 and 41 above. The lumen of catheter 35/45 is capable of receiving fluid under pressure.

n. Regarding claim 43, see claim 24 above.

o. Regarding claim 44, see claim 38 above.

p. Regarding claim 45, see claim 39 above.

Response to Arguments

4. Applicant's arguments filed 10/7/2009 have been fully considered but they are not persuasive.

q. Applicant argues that reference numeral 9 is a sleeve and not a balloon. The Examiner disagrees and believes the sleeve 9 to also be a balloon under broadest reasonable interpretation and the common use of the term.

r. Applicant argues that the catheter is not capable or intended to occlude the aorta or vena cavae. The Examiner disagrees and believes the device of van Moorlegem is perfectly capable of occluding the aorta or vena cavae and any side branches that are connected to the vessel being occluded, even though that is not the intended use.

s. Applicant argues that van Moorlegem does not have a single elongate chamber. This is not convincing as the balloon segments have a common lumen (see figures 1-4).

t. Applicant argues intended use in various different parts of the arguments. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The devices used above are still capable of being used for their intended uses and are also capable of being used as disclosed by the Applicant in a patient under surgery whose heart has been slowed/stopped.

u. Applicant argues that Daneshvar fails to disclose a balloon that is structured to prevent collateral or cross-flow into side branches of the aorta. The Examiner disagrees since Daneshvar discloses a balloon that is used to block flow of the ventricle or wherever the device is placed (Col.4 line 65 to Col.5 line 5). Thus the Examiner maintains that the device of Daneshvar is capable of occluding blood to a main vessel and flow from the side branches of the vessel.

v. Applicant argues that it would not have been an obvious matter of design choice to enlarge the balloon since it would destroy the intent, purpose or function of the device. The Examiner disagrees, Daneshvar is very clear that the catheter and balloon may be reshaped based upon its intended use (Col.6 lines 41-43). Changing the size of the device would only change its ability to

occlude/block in a predictable manner. The device of Daneshvar already solves the particular purpose and stated problem as it is capable of occluding a vessel it is inserted into, elongating it does not further solve the problem, only improve upon its abilities in a predictable manner.

w. Applicant argues that the balloons of van Moorlegem does not disclose separate balloons disposed end-to-end with no gaps therebetween. However, in figure 2, it shows the bases of the balloon segments disposed end-to-end. Thus part of the balloon is disposed end-to-end with no gaps therebetween.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767

/Nicholas D Lucchesi/
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